

REMARKS

Claims 73-74 are pending in the present application. No claims have been amended, cancelled, or added by virtue of this response. Accordingly, claims 73-74 are currently under consideration.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement is filed herewith. The Examiner's consideration of the submitted references is requested.

Priority

Applicants wish to thank the Examiner for acknowledgement of Applicants' claim for the priority benefit of the prior-filed applications. However, the additional priority claims that Applicants requested be added on August 10, 2006, are not on PAIR and no corrected Filing Receipt has been received. A copy of the Supplemental Application Data Sheet and Request for Corrected Filing Receipt previously filed on August 10, 2006, is submitted herewith.

Applicants again respectfully request that the Office issue an updated Filing Receipt to Applicants that accurately reflects the priority claims.

Rejection under 35 U.S.C. § 112

Claim 73 stands rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner has stated that the specification as filed "does not provide a written description or set forth the metes and bounds" of the term "intermolecular." The Examiner also states that the "instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as filed" and that the "specification failed to disclose the 'intermolecular' term." Applicants respectfully traverse.

Applicants respectfully submit that the claim term “intermolecular” is clear to one skilled in the art, particularly in the context of the disclosures of Applicants’ specification. Since the term is well understood and routinely used by those skilled in the art, no definition in the specification is required to meet the requirements of 35 U.S.C. § 112, first paragraph.

Furthermore, Applicants contend that the application as filed provides ample support for the term “intermolecular” as used in claim 73. Applicants contend that one of ordinary skill in the art would recognize support for the language of the claim in the following previously cited passages of the specification: line 22 of page 30 to line 2 of page 31; line 26 of page 34 to line 11 of page 35; and lines 21-23 of page 46. (References to lines and pages of the specification refer to the substitute specification filed on September 29, 2006.) The specification even provides literal support for the term “intermolecular” in lines 21-23 of page 46 which read, “Similar to the use of high shear homogenization, the use of sonication to form protein-coated nanoparticles of water insoluble pharmacologically active agents is believed to operate by crosslinking proteins through the formation of **inter-molecular** disulfide bonds” (emphasis added).

In light of the foregoing remarks, Applicants respectfully request that the rejection of claim 73 under 35 U.S.C. § 112 be withdrawn.

Double Patenting

Claims 73 and 74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,537,579; 5,362,478; 5,498,421; 5,505,932; 5,508,021; 5,512,268; 5,635,207; 5,639,473; 5,650,156; 5,665,382; 5,665,383; 5,916,596; 5,560,933; and 5,439,686.

As noted by the Examiner, Applicants will address these rejections, if maintained, when the pending claims are otherwise found allowable.

Rejection under 35 U.S.C. § 102

Claims 73 and 74 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Liversidge et al. (U.S. Patent No. 5,399,363) in light of Markus et al. The Examiner argues that Liversidge et al. “uses high shear from high shear media mill...and sonication” and therefore assumes that the compositions of Liversidge et al. must have intermolecular crosslinkages. Applicants respectfully traverse.

Inherent anticipation requires that the inherent characteristics in question must necessarily be present in the disclosures of the prior art. See MPEP § 2112(IV). “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).” See MPEP § 2112(IV). Furthermore, “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.’ *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).” See MPEP § 2112(IV).

Liversidge et al. fails to inherently anticipate the compositions of claims 73 and 74, because the compositions as claimed have characteristics that do not necessarily flow from the teachings of Liversidge et al. Even if Liversidge et al. does disclose methods involving the use of a high shear media mill or sonication, the Examiner has provided no evidence to suggest that the methods, as disclosed in Liversidge et al., would necessarily result in the production of compositions comprising albumin that is crosslinked by intermolecular disulfide bonds as recited in claim 73. For example, techniques such as sonication can be performed under different conditions, such as using different energy levels, and thereby produce different results. Notably, the passage in Liversidge et al. regarding sonication that was cited by the Examiner in the Office Action (line 57 of column 6 of Liversidge et al.) is completely silent with respect to the energy level used. Thus, it is not reasonable to conclude that Applicants’ claimed articles of manufacture would necessarily flow

from the disclosures of Liversidge et al. simply because the reference teaches general methods such as sonication.

Furthermore, and most importantly, the Liversidge et al. reference *itself* clearly states that the “individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages” (lines 57 to 59 of column 4 of Liversidge et al.). In light of this express statement in the Liversidge et al. reference itself regarding the nature of the particles produced by the methods taught in that reference, Applicants respectfully submit that any assumption that the particles produced by the methods taught in Liversidge et al. would necessarily produce compositions comprising albumin that is crosslinked by intermolecular disulfide bonds is simply not reasonable.

In light of the foregoing remarks, Applicants respectfully request that the rejection of claims 73 and 74 under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 420052000126. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By


Alicia J. Hager
Registration No.: 44,140

MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-4296